## UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

## DECLARATION OF CHARLES B. KLEIN IN SUPPORT OF DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

## I, Charles B. Klein, declare:

- 1. I am an attorney at law, admitted to practice in this Court for this matter. I am a partner with the law firm Winston & Strawn LLP, counsel of record for Paddock Laboratories, Inc. and Cerovene, Inc., and am authorized to make this Declaration in that capacity.
- I submit this Declaration in support of Defendants' Opening Claim
   Construction Brief. The statements contained herein are based on my own personal knowledge unless otherwise stated.
- Attached hereto as Exhibit 1 is a true and accurate copy of U.S. Patent No.
   7,101,574 B1.
- 4. Attached hereto as Exhibit 2 is a true and accurate copy of U.S. Patent No. 7,863,331 B2.
- 5. Attached hereto as Exhibit 3 is a true and accurate copy of U.S. Patent No. 4,800,079.

- 6. Attached hereto as Exhibit 4 is a true and accurate copy of Foreign Pat. No. WO 98/00116.
- 7. Attached hereto as Exhibit 5 is a true and accurate copy of the Abstract of Foreign Pat. No. WO 82/01649.
- 8. Attached hereto as Exhibit 6 is a true and accurate copy of U.S. Patent No. 7,101,574.
- 9. Attached hereto as Exhibit 7 is a true and accurate copy of Foreign Pat. No. EP 0 793 958 A2, as translated from German by Ethypharm.
- 10. Attached hereto as Exhibit 8 is a true and accurate copy of Joint Claim Construction Statement, No. 11-md-2241, DE 3 (S.D.N.Y. filed June 15, 2011).
- 11. Attached hereto as Exhibit 9 is a true and accurate copy of Plaintiffs' Answer to Paddock's Counterclaims, No. 11-cv-0668, DE 12 (S.D.N.Y. filed Feb. 28, 2011).
- 12. Attached hereto as Exhibit 10 is a true and accurate copy of Manual of Patent Examining Procedure § 201.08, at p. 200-53–54, July 2010 (8th ed., Rev. 8).
- 13. Attached hereto as Exhibit 11 is a true and accurate copy of "micro," Merriam-Webster's Medical Dictionary (2007), available at http://dictionary.reference.com/browse/micro.
- 14. Attached hereto as Exhibit 12 is a true and accurate copy of "micron," Merriam-Webster's Medical Dictionary (2007), available at http://dictionary.reference.com/browse/micron.
- 15. Attached hereto as Exhibit 13 is a true and accurate copy of Isaac Ghebre-Sellassie, *Pellets: A General Overview*, *in Pharmaceutical Pelletization Technology*, 1 (Isaac Ghebre-Sellassie ed., 1989).

- 16. Attached hereto as Exhibit 14 is a true and accurate copy of Dow, METHOCEL CELLULOSE ETHERS TECHNICAL HANDBOOK (2002).
- 17. Attached hereto as Exhibit 15 is a true and accurate copy of REMINGTON: THE SCIENCE & PRACTICE OF PHARMACY (Paul Beringer, et al. eds., 21st ed. 2005).
- 18. Attached hereto as Exhibit 16 is a true and accurate copy of sections from Handbook of Pharmaceutical Excipients (5th ed. 2006).
- 19. Attached hereto as Exhibit 17 is a true and accurate copy of 10/030,262Prosecution History, Claims (Jan. 8, 2002).
- 20. Attached hereto as Exhibit 18 is a true and accurate copy of 10/030,262 Prosecution History, Applicant Argument Made in an Amendment (May 5, 2004).
- 21. Attached hereto as Exhibit 19 is a true and accurate copy of 10/030,262 Prosecution History, Applicant Argument Made in an Amendment (Mar. 18, 2005).
- 22. Attached hereto as Exhibit 20 is a true and accurate copy of 10/030,262 Prosecution History, Amendments to the Claims (May 18, 2005).
- 23. Attached hereto as Exhibit 21 is a true and accurate copy of 10/030,262 Prosecution History, Applicant Argument Made in an Amendment (May 18, 2005).
- 24. Attached hereto as Exhibit 22 is a true and accurate copy of 10/030,262 Prosecution History, Examiner Interview Summary Record (Sep. 20, 2005).
- 25. Attached hereto as Exhibit 23 is a true and accurate copy of 10/030,262 Prosecution History, Amendments to the Claims (Oct. 21, 2005).
- 26. Attached hereto as Exhibit 24 is a true and accurate copy of 10/030,262 Prosecution History, Applicants Arguments Made in an Amendment (Oct. 21, 2005).

- 27. Attached hereto as Exhibit 25 is a true and accurate copy of 10/030,262 Prosecution History, Second Decl. of George Bobotas, Ph.D. (Feb. 21, 2006).
- 28. Attached hereto as Exhibit 26 is a true and accurate copy of 10/030,262 Prosecution History, Applicant Remarks Made in an Amendment (Feb. 21, 2006).
- 29. Attached hereto as Exhibit 27 is a true and accurate copy of 10/030,262 Prosecution History, Examiner's Response to Arguments in Non-Final Rejection (March 14, 2006).
- 30. Attached hereto as Exhibit 28 is a true and accurate copy of 10/030,262 Prosecution History, Applicant Arguments Made in an Amendment (Apr. 13, 2006).
- 31. Attached hereto as Exhibit 29 is a true and accurate copy of 10/030,262 Prosecution History, Notice of Allowance (July 12, 2006).
- 32. Attached hereto as Exhibit 30 is a true and accurate copy of 10/677,861 Prosecution History, Claims & Abstract (Mar. 10, 2003).
- 33. Attached hereto as Exhibit 31 is a true and accurate copy of 10/677,861 Prosecution History, Applicant Remarks Made in an Amendment (Oct. 26, 2007).
- 34. Attached hereto as Exhibit 32 is a true and accurate copy of 10/677,861 Prosecution History, Applicant Arguments Made in an Amendment (Nov. 7, 2008).

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: June 21, 2011 /s/ Charles B. Klein

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